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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,310	11/21/2003	Paul G. Brunetta	P1979R1	3292

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,310	BRUNETTA ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/21/03*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-46 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 19, 29-32, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody or conjugated antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **psoriasis**, classified in Class 424, subclass 130.1.

2. Claims 20, and 33-36, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **endometriosis**, classified in Class 424, subclass 130.1.

3. Claim 21, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **scleroderma**, classified in Class 424, subclass 130.1.

4. Claims 22-23, 27, and 37-41, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is a **specific vascular disease**, classified in Class 424, subclass 130.1.

5. Claim 24, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **colon polyps**, classified in Class 424, subclass 130.1.

6. Claim 25, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **fibroadenoma**, classified in Class 424, subclass 130.1.

7. Claims 26-27 and 42-46, drawn to **a method of treating** a specific non-malignant disease or disorder comprising administering to the mammal a therapeutic effective amount of an antibody which binds ErbB2 and further comprising administering a specific second therapeutic agent, wherein the non-malignant disease is **a specific respiratory disease**, classified in Class 424, subclass 130.1.

8. Claim 28, drawn to a **an article** of manufacture comprising a container and a composition comprising an antibody which binds ErbB2 and a package insert, classified in Class 435, subclass 810.

Linking claims 1-18 will be examined along with any Groups 1-7 if any one of said Groups is elected.

Claims 1-18 link inventions 1, 2, 3, 4, 5, 6, or 7. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or

nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups 1-7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).
The methods of groups 1-7 as claimed are all unrelated as non-malignant diseases differ with respect to their etiology, and therapeutic endpoints.

Inventions of Group 8 and Groups (1-7) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the kit as claimed can be used in treating disease as opposed to its use in detection assays.

III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the different diseases recited and the various therapeutic agents and endpoints. A prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

IV. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:
If Group 1 is elected, the Applicant is required to elect a specific method of treating psoriasis comprising (1) a specific second therapeutic agent such as the ones recited in claims15 and 32, and (2) whether the antibody is conjugated or not conjugated with a cytotoxic agent as set forth in claim 12-14. These therapeutic agents such as ErbB antagonist, immunosuppressive agent, chemotherapeutic agent, cytotoxic agent, growth inhibitory agent, EGFR target drug, tyrosine kinase inhibitor, anti-angiogenic agent, anti-hormonal compound, cardioprotectant, cytokines,

cytotoxic agent conjugate antibody and the ones recited in claim 32 differ with respect to their structure, physiochemical properties and mode of action. Therefore, they are patentably distinct.

If Group 2 is elected, the Applicant is required to elect a specific method of treating endometriosis comprising (1) a specific second therapeutic agent such as the ones recited in claims 15 and 36 and (2) whether the antibody is conjugated or not conjugated with a cytotoxic agent as set forth in claim 12-14. These therapeutic agents such as ErbB antagonist, immunosuppressive agent, chemotherapeutic agent, cytotoxic agent, growth inhibitory agent, EGFR target drug, tyrosine kinase inhibitor, anti-angiogenic agent, anti-hormonal compound, cardioprotectant, cytokines, cytotoxic agent conjugate antibody and the ones recited in claim 36 differ with respect to their structure, physiochemical properties and mode of action. Therefore, they are patentably distinct.

If Group 4 is elected, the Applicant is required to elect a method of treating a (1) specific vascular disease such as the ones recited in claim 38, (2) a specific second therapeutic agent such as the ones recited in claims 15 and 41, and (3) whether the antibody is conjugated or is not conjugated with a cytotoxic agent as set forth in claim 12-14. These method of treating the various vascular diseases using distinct composition comprising different antibodies that differs with respect to their binding specificity such as blocking binding of 2C4 to ErbB2 versus binding to ErbB2 and therapeutic agents where these agents such as ErbB antagonist, immunosuppressive agent, chemotherapeutic agent, cytotoxic agent, growth inhibitory agent, EGFR target drug, tyrosine kinase inhibitor, anti-angiogenic agent, anti-hormonal compound, cardioprotectant, cytokines, cytotoxic agent conjugate antibody and the ones recited in claim 41 differ with respect to their structure, physiochemical properties and mode of action. Therefore, they are patentably distinct.

If Group 7 is elected, the Applicant is required to elect a method of treating a (1) specific respiratory disease such as the ones recited in claim 43, (2) a specific second drug such as the ones recited in claims 15 and 46, and (3) whether the antibody is conjugated or is not conjugated with a cytotoxic agent as set forth in claim 12-14. The method of treating various respiratory diseases using distinct composition comprising different antibodies that differs with respect to their binding specificity such as blocking binding of 2C4 to ErbB2 versus binding to ErbB2; these therapeutic agents such as ErbB antagonist, immunosuppressive agent, chemotherapeutic agent,

cytotoxic agent, growth inhibitory agent, EGFR target drug, tyrosine kinase inhibitor, anti-angiogenic agent, anti-hormonal compound, cardioprotectant, cytokines and cytotoxic agent conjugate antibody, and the ones recited in claim 46 differ with respect to their structure, physiochemical properties and mode of action. Therefore, they are patentably distinct.

V. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 29, 33, 37 and 42 are generic.

VI. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

VII. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

VIII. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

IX. Due to the complexity of the claimed invention an oral restriction was not made.

X. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

XI. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

XII. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

XIII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

XIV. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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